Varian Medical Systems, Inc.
% Peter J. Coronado
Sr. Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

May 22, 2023

Re: K223839
Trade/Device Name: TrueBeam™, TrueBeam STx™, Edge™, VitalBeam
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: April 20, 2023
Received: April 20, 2023

Dear Peter Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.05.22 17:25:26 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223839

Device Name
TrueBeam, TrueBeam STx and Edge Radiotherapy Delivery System;
VitalBeam

Indications for Use *(Describe)*
TrueBeam-TrueBeam STx-Edge:

The TrueBeam™, TrueBeam STx and Edge™ Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

The TrueBeam, TrueBeam STx, and Edge Systems may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation, and skull base tumors), and medically refractory essential tremor (indicated for adults only).

VitalBeam:

VitalBeam® is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

VitalBeam may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation, and skull base tumors).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PREMARKET NOTIFICATION 510(k) Summary **K223839**
TrueBeam and VitalBeam Radiotherapy Treatment System

The following information follows the format of 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA94304
Primary Contact Person:	Peter J. Coronado Sr. Director Regulatory Affairs Phone: (650) 424.6320 Fax: (650) 646.9200 E-mail: submissions.support@varian.com
Date Prepared:	18 May 2023
Proprietary Name:	TrueBeam™ /TrueBeam STx™/Edge™/VitalBeam
Classification Name:	Medical charged-particle radiation therapy system
Regulation:	21CFR892.5050
Regulatory Class	Class II
Product Code:	IYE
Common/Usual Name:	Linear accelerator radiation therapy system
Predicate Devices:	TrueBeam Radiotherapy System and Accessories
Device Description:	The TrueBeam and VitalBeam Radiotherapy System is a medical linear accelerator that delivered therapeutic radiation to patient in accordance with the physician's prescription. The system consists of two major components – a photon, electron and diagnostic kV X-ray radiation beam producing component that is installed in a radiation-shielded vault and a control console area located outside the treatment room.
Intended Use	The intended use is the same as the predicate. **TrueBeam-TrueBeam STx-Edge:** The TrueBeam ™ radiotherapy delivery system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated. **VitalBeam:** The VitalBeam system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Indications for Use:

TrueBeam-TrueBeam STx-Edge:

The TrueBeam™, TrueBeam STx and Edge™ Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

The TrueBeam, TrueBeam STx, and Edge Systems may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation, and skull base tumors), and medically refractory essential tremor (indicated for adults only).

VitalBeam:

VitalBeam® is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

VitalBeam may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors,

	arteriovenous malformation, cavernous malformation, and skull base tumors).
Technological Characteristics:	The device has the same technological characteristics as the previously cleared TrueBeam device K213977. The indications for use have expanded to include "medically refractory essential tremor" in TrueBeam™, TrueBeam STx and Edge™ System. This submission does not include any other device modification.
Summary of Performance Testing:	The predicate and subject device have equivalent performance specifications and have the same principle of operation. The results of the verification, validation and safety standards testing (Predicate device - K213977) demonstrates that there are no changes to the safety profile of the device.
Summary of Clinical Data:	Stereotactic Radiosurgery (SRS) has been used for decades to treat tremor conditions. In a literature review, over 1300 patients were treated with SRS for tremor conditions with similar outcomes and complication rates as traditional surgical options. The attributes of advanced target localization, beam collimation, and patient immobilization are common to both linear accelerators and Gamma Knife, allowing for both devices to deliver comparable doses to precisely-defined targets. Linear accelerators are in routine clinical use for SRS treatments and recent publications report tremor improvement and complication rates for linear accelerator-based SRS comparable to those achieved with the Gamma Knife. The majority of studies reporting on the use of SRS for the treatment of tremor conditions include a discussion on the importance of advanced imaging and a dedicated/experienced treatment team in order to properly localize, immobilize, and treat these patients. In conclusion, linear accelerator-based SRS for medically refractory essential tremor is reported to be a safe and efficacious treatment option in situations where other treatment options are not available or are otherwise contraindicated.

Argument for Substantial Equivalence to the Predicate Device

The subject device and predicate device have the same intended use of stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients. The expansion of the indications for use to include "medically refractory essential tremor" does not affect the design/principle of operation and does not introduce changes in the risk profile.

The technological characteristics and features of the subject device remain unchanged from the previous submission (Predicate device - K213977). There are no other modifications to predicate device. The predicate and subject device have equivalent performance specifications and have the same principle of operation. The verification, validation and safety testing standards that support HET v3.0 (TrueBeam-TrueBeam STx-Edge and VitalBeam) have been performed for the predicate device.

Based on the methods of evaluation and the data from the clinical literature, Varian believes that the subject device is substantially equivalent to the predicate device.